Remarks

Claims1, 3-6, 11, 22, 24, 29 and 49-52 are amended. Claims 2, 7-10, 21, 27-28, 31-32 and 35-40 are canceled. Claims 1, 3-6, 11-20, 22-26, 29-30 and 49-52 are pending.

Objection to the Specification

The specification was objected to as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e., failing to provide an enabling disclosure. Applicant respectfully submits that the amendments to the claims render the objection moot and respectfully requests withdrawal of the objection.

The 35 U.S.C. §112, First Paragraph, Rejections

Claims 1-32, 35-40 and 49-52 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant are that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention. These rejections are respectfully traversed. Applicants assert that the disclosure in the instant specification fully complies with the "written description" requirement of 35 U.S.C. § 112, first paragraph.

Applicant respectfully submits that the amendments to the claims render the rejection moot. Furthermore, Applicant respectfully submits that the claims are limited to antiserum specific for peptides e.g., antiserum which recognize Fibrinopeptide B (FPB) peptides and/or des-arginine Fibrinopeptide B (des-arginine FPB) peptides comprising amino acid sequence SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5 or SEQ ID NO:6.

The high state of the art of antiserum production, antibody selection and the high state of knowledge regarding the structure of antibodies provides one of ordinary skill in the art with the sufficient background to fully understand and practice the present invention. The function of the written description requirement is to ensure that a patent is granted to inventors who had possession, as of the filing date of the application relied on, of the specific subject matter later

claimed by them; how the specification accomplishes this is not material. *In re Smith*, 178 U.S.P.Q. 620 (C.C.P.A. 1973). Therefore, the test for written description under 35 U.S.C. § 112, first paragraph, is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that Applicants had possession of the subject matter later claimed. M.P.E.P. § 2163.02. See also, *In re Kaslow*, 217 U.S.P.Q. 1089 (Fed. Cir. 1983). What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. M.P.E.P. § 2163.II.A.3(a) (citing to *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986)). An inventor is not required to describe every detail of the invention.

Applicant respectfully submits that the present specification describes and claims antiserum that bind several antigens and provides clear guidance for production of this antiserum through the use of these antigens, e.g., Fibrinopeptide B antigen. Furthermore, the production of antiserum is well known in the relevant art.

While the application states that an antiserum with "the best reactivity profile" was used, this does not mean that the other antiserums prepared were not useful or did not fall within the range now claimed. Furthermore, Applicant respectfully submits that one of skill in the art would be able to, from the disclosure in the specification and the knowledge available to the art worker, prepare the antiserum claimed in the instant application. Thus, the present application provides an adequate written description of the claimed invention and therefore meets the written description requirement under 35 U.S.C. § 112, first paragraph.

Claims 7, 9-10, 27, 31, 36 and 39 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description or enablement. The cancellation of claims 7, 9-10, 27, 31, 36 and 39 renders this rejection moot. Thus, Applicant respectfully requests withdrawal of this rejection.

The 35 U.S.C. §112, Second Paragraph, Rejections

Claims 1-32, 35-40 and 49-52 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. These rejections are respectfully traversed.

Applicant respectfully submits that the amendments to claims 1, 29 and 52 render the rejection moot as it pertains to claims 1, 29 and 52 and claims dependent thereon.

With regards to claim 11, the FPB:detection agent complex is present in the sample as a result of the addition of detection agent, e.g., antiserum, to a sample which contains the antigen, e.g., FPB. The antibodies in the antiserum bind the antigen and form a FPB:detection agent complex. The presence of complexes can be quantitated and provide information regarding the amount of peptide (antigen; FPB) in a sample. This is routinely carried out in this art area.

Thus, Applicant requests that the rejection of the claims under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 102 Rejections

Claims 1-7, 9-15, 21-27, 35, 36, 49, 51 and 52 were rejected under 35 U.S.C. § 102(e)(2) for anticipation by Kudryk et al. (US 5,876,947) and under 35 U.S.C. § 102(a) by Kudryk *et al.* (WO 99/05176). These two Kudryk *et al.* references are identical in content. Therefore, the rejections are addressed collectively below. Applicants respectfully traverse these rejections.

The standard for anticipation is one of strict identity, and to anticipate a claim for a patent a single prior art source must contain all its elements. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q.2d 90 (Fed. Cir. 1986); *In re Dillon*, 16 U.S.P.Q.2d 1987 (Fed. Cir. 1990). Furthermore, there must be no difference between the claimed invention and the disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991).

Kudryk et al. disclose a monoclonal antibody produced by a hybridoma cell line referred to as P10. The "P10" antibody is disclosed to specifically bind to fibrinogen, fibrinopeptide B, des-Arg fibrinopeptide B, N-DSK and related proteins (see, for example, page 5, lines 7-13; page 12, lines 17-19; Figures 1C, 2C and 4 of WO 99/05176). Kudryk et al. disclose that in a competitive ELISA, the P10 antibody was found to be "substantially more reactive with intact fibrinogen" than FPB or des-Arg FPB (page 31, lines 17-19 of WO 99/05176). Kudryk et al. further disclose that the clinical use of P10 is limited because of such strong cross-reactivity with fibrinogen (paragraph bridging pages 31-32 of WO 99/05176). Thus, Kudryk et al. do not disclose/anticipate the presently claimed antiserum.

As discussed above, Kudryk et al. disclose that P10 is very reactive to fibrinogen in a competitive ELISA. Figure 7 of Kudryk et al.(WO 99/05176) illustrates the dose-response

reactivity data collected from the assay that have been linearized by means of logit transforms (page 31, lines 14-15 of WO 99/05176). In Figure 7 of Kudryk et al., the intercept of LOGIT = 0 represents the IC_{50} for the various antigens (i.e., fibrinogen (170kDa), Bβ 1-13 (des-arginine FPB) and Bβ 1-14 (FPB). According to Figure 7 of Kudryk et al., the IC_{50} of fibrinogen is about 1-2 pmol.ml (nM), the IC_{50} of FPB is about 100 nM, and the IC_{50} of des-arginine FPB is about 100 nM. Thus, Kudryk et al. disclose that the P10 antibody has a much stronger affinity for intact fibrinogen than for free FPB.

Contrary to the presently claimed invention, the Kudryk et al. antibody binds fibrinogen fifty- to one hundred-fold more strongly than it binds free FPB. Furthermore, this binding profile makes P10 clinically limited, because of the strong cross-reactivity with fibrinogen (which would likely lead to an erroneous result if any amount of fibrinogen were to remain in the clinical sample; see, for example the paragraph bridging pages 31-32 of Kudryk et al. (WO 99/05176)).

Thus, Kudryk et al. do not disclose/anticipate the presently claimed antiserum. Therefore, Applicant respectfully request that the 102(e)/102(a) rejections of the claims be withdrawn.

Claims 38 and 39 were rejected under 35 U.S.C. § 102(e)(2) and 102(a) for anticipation by Kudryk et al. The cancellation of claims 38 and 39 renders these rejections moot. Thus, Applicant respectfully requests withdrawal of these rejections.

The 35 U.S.C. § 103 Rejections

Claims 38 and 40 were rejected under 35 U.S.C. § 102(b) for anticipation by, or under 35 U.S.C. 103(a) s being unpatentable over, Qureshi et al in light of Eckharde e tal., Bilezikian et al., and Wilner et al. The cancellation of claims 38 and 39 renders this rejection moot. Thus, Applicant respectfully requests withdrawal of this rejection.

The Examiner rejected claims 1-17 and 21-40 under 35 U.S.C. § 103(a) as being unpatentable over Kudryk et al. (US 5,878,947) or Kudryk et al. (WO 99/05176), in view of Eckhardt et al. (J. Clin. Invest. 67:809, 1981). Applicants respectfully traverse these rejections.

As discussed above, Kudryk et al. do not disclose or suggest the antiserum as presently claimed. Eckhardt et al. do not do not compensate for the deficiencies of the primary reference. Thus, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 103 be withdrawn.

Double Patenting Rejection

Claims 38-40 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-23 of U.S. Patent No. 6,673,561, if necessary, in view of Kudryk et al. (US 5,876,957 or WO 99/05176). The cancellation of claims 38 -40 renders this rejection moot. Thus, Applicant respectfully requests withdrawal of this rejection.

Claims 1-14, 18-32, 35-37, 49, 51 and 52 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-23 of U.S. Patent No. 6,673,561, if necessary, in view of Kudryk et al. (US 5,876,957 or WO 99/05176). While not conceding to the Examiner's position, Applicant's provides herewith a terminal disclaimer to obviate this rejected and further prosecution of this application.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney, **Monique M. Perdok Shonka (612) 373-6905,** to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, MS RCE, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22 day of February 2008.

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